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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,898	01/25/2006	Basil S Shorosh	CGL020273US01	6095
38550 7590 05/21/2009 CARGILL, INCORPORATED P.O. Box 5624 MINNEAPOLIS, MN 55440-5624				
EXAMINER				
MEHTA, ASHWIN D				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/565,898

Applicant(s)

SHORROSH ET AL.

Examiner

Ashwin Mehta

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-7, 9, 21 and 26-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-7, 8, 21, 26-28 is/are rejected.
- 7) ☒ Claim(s) 10 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 28, 2009 has been entered.
2. The rejection of claims 16, 24, and 25 under 35 U.S.C. 112, 1st paragraph, is moot, in light of their cancellation.

Claim Objections

3. Claim 10 remains objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112

4. Claims 1, 3-7, 9, 21, and 26-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

claimed invention, for the reasons of record stated in the Office action mailed January 29, 2009. Applicants traverse in the papers filed April 28, 2009. Applicants' arguments were fully considered but were not persuasive.

Applicants argue that the nucleic acid of SEQ ID NO: 1 is representative of the claimed genus of nucleic acids having at least 90% identity to SEQ ID NO: 1 and capable of promoting expression of an operably linked heterologous nucleic acid in a plant cell. Applicants argue that the claimed nucleic acids contain a highly similar nucleotide sequence, and accordingly the necessary common attributes of all the sequences claimed (response, paragraph bridging pages 5-6). However, sequence identity alone does not describe the common attributes shared among the species of the claimed genus that is required for functional activity. Further, SEQ ID NO: 1 is not representative of sequences that differ from it. Applicants note that the level of identity recited in the claims is higher than that of Example 11A of the Revised Written Description Training Materials (March 25, 2008), thereby further decreasing any potential variation between species. Applicants also point to Example 10 of the Training Materials. Applicants argue that one of ordinary skill can envision every possible sequence that satisfies the criteria of the claimed genus with the aid of a computer. Applicants argue that the specification identifies a number of regulatory motifs in SEQ ID NO: 1, including the CAAT-box motif, TATA box, CTCATCTA motif, and four motifs reported to confer seed-specific expression and at least one motif reported to be needed for endosperm and embryo specific expression. Applicants argue that the data in Examples 3 and 4 of the specification demonstrate SEQ ID NO: 1 is useful for directing expression in seeds and embryos (response, pages 6-7). However, as noted in the previous Office action, many of the elements recited in Table 1, are not further discussed in the

specification as being required for activity of SEQ ID NO: 1. Table 1 also mentions a "GCCATTG" sequence, the significance of which is unknown. Thirteen "GATA" box motifs are identified as present in SEQ ID NO: 1, which is involved in light regulation. Yet, the specification does not mention that SEQ ID NO: 1 is regulated by light. A "SEF1" sequence is identified, but its significance in SEQ ID NO: 1 is unknown. Sequences are noted in Table 1 for ABA-responsiveness; light regulation; an AP2-like binding consensus for Arabidopsis transcription factor RAV1; a motif in a soybean 7S globulin gene; gibberellin responsiveness; cis-elements found in phenylalanine ammonia lyase genes; elements for ethylene responsiveness. Yet the specification does not describe SEQ ID NO: 1 as responding to light, ABA, gibberellin, or ethylene, for example. Applicants' response mentions that an element, CA(n), is present which confers endosperm specificity. Yet, the working examples do not show endosperm specificity for SEQ ID NO: 1. A sequence is noted only for being present in an oleosin promoter, while SEQ ID NO: 1 is a 2S globulin gene promoter. One domain is even described as "Unknown". The importance of these domains to the functional activity of SEQ ID NO: 1 is unknown. There is nothing in the claims indicating that each of the domains listed in Table 1 are also to be present. The functional activity of sequences that differ from SEQ ID NO: 1 and which do not contain these domains is unknown. Further, it is noted that numerous domains are noted in Table 1 as conferring seed or embryo specificity. However, they are scattered throughout the 2400 base sequence of SEQ ID NO: 1. The specification does not actually describe which of these sequences actually are required for transcriptional activity, or which ones confer seed and embryo specificity to SEQ ID NO: 1. Further, given that these domains are scattered throughout the 2400 base sequence of SEQ ID NO: 1, the fragments encompassed by

claims 26-28 would not retain all of them. The nucleic acids encompassed by claims 26-28 could not have the functional activity of SEQ ID NO: 1.

5. Claims 1, 3-7, 9, 21, and 26-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO: 1, does not reasonably provide enablement for isolated nucleic acids that differ from SEQ ID NO: 1 and have its activity of promoting expression of an operably linked heterologous nucleic acid. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, for the reasons of record stated in the Office action mailed January 29, 2009. Applicants traverse in the papers filed April 28, 2009. Applicants' arguments were fully considered but were not persuasive.

Applicants argue that one of ordinary skill can determine if a nucleic acid has at least 90% identity to SEQ ID NO: 1 and determine if it functions as a regulatory element without undue experimentation (response, page 7, 2nd full paragraph). Applicants argue that the specification provides detailed guidance regarding the location of regulatory motifs in SEQ ID NO: 1 that are involved in promoting expression, which along with assays to confirm activity in a plant cell, is sufficient to enable one of ordinary skill in the art to make and use the claimed invention without undue experimentation (response, pages 7-8). However, as discussed in the previous Office action, the importance of the regions identified in Table 1 to the activity of SEQ ID NO: 1 was not confirmed experimentally. Many of these elements are described as required for activities which the specification does not mention is possessed by SEQ ID NO: 1. For

example, sequences are noted for ABA-responsiveness; light regulation; an AP2-like binding consensus for Arabidopsis transcription factor RAV1; a motif in a soybean 7S globulin gene; gibberellin responsiveness; cis-elements found in phenylalanine ammonia lyase genes; elements for ethylene responsiveness. Yet the specification does not teach SEQ ID NO: 1 as responding to light, ABA, gibberellin, or ethylene. An element, CA(n), is listed, which confers endosperm specificity, and which the working examples do not show for SEQ ID NO: 1. A sequence is noted only for being present in an oleosin promoter. One domain is even described as "Unknown". The importance of these domains to the functional activity of SEQ ID NO: 1 is unknown. Example 2 on page 19 indicates that these regions were identified by BLAST analysis as having sequence similarity to plant and non-plant genomic regions. However, which of these regions, if any, are actually required for functional activity of SEQ ID NO: 1 is unknown.

Further, while several domains are noted in Table 1 as being associated with seed or embryo specificity, they are scattered throughout the 2400 base sequence of SEQ ID NO: 1, and there is no indication as to whether they actually do confer seed and/or embryo specificity to the SEQ ID NO: 1. The fragments encompassed by claims 26-28 would not be expected to retain the activity of SEQ ID NO: 1, as they would not retain all of the domains recited in Table 1. In the absence of further guidance, undue experimentation would be required by one skilled in the art to determine which, if any, of the supposed regulatory regions mentioned in Table 1 are actually required for the transcriptional activity of SEQ ID NO: 1. Undue experimentation would also be required to determine the 10% of the sequences of SEQ ID NO: 1 that can be altered, and what to change them to, without affecting its transcriptional activity.

Contact Information

Any inquiry concerning this or earlier communications from the Examiner should be directed to Ashwin Mehta, whose telephone number is 571-272-0803. The Examiner can normally be reached from 8:30 A.M to 6:00 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached at 571-272-0975. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

May 20, 2009

/Ashwin Mehta/
Primary Examiner, Art Unit 1638